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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE INSULIN PRICING LITIGATION	Civil Action No. 17-699(BRM)(LHG) **ORAL ARGUMENT REQUESTED**

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT (COUNTS 1-6)

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Defendants Novo Nordisk Inc. ("Novo Nordisk"), Eli Lilly and Company ("Lilly"), and Sanofi-Aventis U.S. LLC ("Sanofi") (together, "defendants") respectfully submit this memorandum of law in support of their Motion to Dismiss the Consolidated Amended Class Action Complaint (the "complaint" or "CAC") pursuant to Federal Rule of Civil Procedure 12(b)(6).

PRELIMINARY STATEMENT

Through this lawsuit, plaintiffs seek to criminalize a fundamental aspect of the pharmaceutical industry. Plaintiffs' grievance is that pharmaceutical manufacturers pay rebates to entities called pharmacy benefit managers ("PBMs") to ensure that the manufacturers' prescription medications are available to consumers, but that these rebates are not passed on to plaintiffs at the pharmacy counter. From this, plaintiffs conclude that defendants must be engaged in criminal fraud. But plaintiffs do not allege that they were deceived about the price they paid for insulin at the pharmacy or that they were promised the benefit of any rebate. Indeed, none of the allegations in plaintiffs' 200-page-long complaint shows that defendants have done anything fraudulent, unfair, or unconscionable.

The rebates about which plaintiffs complain arise from negotiations between the defendant manufacturers and PBMs. PBMs are hired by commercial and government-run health insurers to manage their prescription drug costs. As the complaint alleges, the rebates paid to PBMs are integral to defendants' ability to

make their insulin medications available to consumers. In fact, the three largest PBMs together govern access to prescription medication for approximately 180 million people. As a result, the PBMs determine with their health insurer clients whether they will cover a particular drug and how much an insured individual will pay for it. These determinations often dictate which insulin an insured individual uses—for example, Novo Nordisk's Levemir or Sanofi's Lantus.

Because of their market position, the PBMs are able to extract substantial pricing concessions (i.e., "rebates") from prescription drug manufacturers.[1] As plaintiffs allege, the PBMs demand rebates from the manufacturers in exchange for placing manufacturers' products on insurance formularies. And, as plaintiffs further allege, the PBMs pass along "a large portion" of these rebates to their health insurer clients. CAC ¶ 185. The fact that manufacturers pay rebates to PBMs in order to obtain access to patients is widely known. It is also entirely rational and lawful for manufacturers to discount their products (through the

[1] Before making the strategic decision to toll their claims against the PBMs, some plaintiffs alleged that the PBMs named as defendants in their complaints—CVS Health, Express Scripts, and OptumRx—are "engaging in extortion" by extracting rebates from manufacturers. *See Boss, et al. v. CVS Health Corp., et al.*, Case No. 2:17-cv-01823 (D.N.J. Mar. 17, 2017), Dkt. No. 1 ¶ 25; *see also Christensen, et al. v. Novo Nordisk Inc., et al.*, Case No. 3:17-cv-02678 (D.N.J. Apr. 20, 2017), Dkt. No. 1 ¶ 10 ("The contest rigged up by the PBMs creates the incentive and framework for the Drug Manufacturers to raise their insulin list prices.").

payment of rebates) in exchange for having their products appear on formularies that insurers use to make coverage decisions for the vast majority of patients.

The crux of plaintiffs' complaint is that the rebates defendants pay to PBMs do not directly reduce the amount that consumers pay to pharmacies. This does not state a legal claim. A manufacturer's decision to offer a rebate for formulary placement does not defraud the end consumer, and plaintiffs cannot blame the *manufacturers* for how *PBMs and health insurers* distribute (or retain) the rebates that they receive. Although discounting is a common and permissible feature of many industries, plaintiffs try to portray PBM rebates as fraudulent by asserting that defendants misrepresented that their "benchmark prices" reflected "the 'rebates' drug manufacturers offer PBMs." *Id.* ¶ 11. But plaintiffs do not identify a single instance in which a defendant represented that its "benchmark prices" accounted for PBM rebates—or even that plaintiffs believed that to be true. Indeed, plaintiffs do not—because they cannot—even allege that manufacturers set the prices that pharmacies charge consumers for medication. And to the extent that insured consumers are unhappy that they do not receive the benefit of rebates paid to their insurers and PBMs, their complaint is not with defendants.

Defendants acknowledge that pharmaceutical pricing is an important issue, especially given how recent trends in the design of insurance benefits have affected certain patients' out-of-pocket costs. As plaintiffs recognize, manufacturer rebate

payments to PBMs are not unique to sales of insulin.[2] It is how the entire branded pharmaceutical industry functions. As a result, the relief plaintiffs seek in this litigation would not only require this Court to regulate sales of insulin, but also would have an impact on the entire pharmaceutical industry at large. While the pricing system may benefit from reforms, this issue is not properly addressed via *in terrorem* claims seeking treble-damages liability under the federal racketeering statute or via conclusory invocations of every state's consumer-protection laws.

As demonstrated below, the Court should dismiss plaintiffs' RICO and New Jersey Consumer Fraud Act ("NJCFA") claims (i.e., Counts 1 through 6). The Court should also dismiss plaintiffs' myriad other state law claims (i.e., Counts 7 through 60).[3]

[2] Plaintiffs suggest that the *amount* of rebates paid by insulin manufacturers to PBMs in some way renders insulin pricing deceptive. This theory has no basis in law and no logical limit.

[3] In a separate brief contemporaneously filed with this one, defendants explain why plaintiffs' state law claims (in addition to plaintiffs' NJCFA claims) all fail. *See* Defendants' Memorandum of Law in Support of Motion to Dismiss the Consolidated Amended Class Action Complaint (Counts 7-60) ("State Law Brief"). Because plaintiffs fail to plead facts showing that defendants did anything fraudulent, unfair, or unconscionable—as demonstrated in this brief—all of their state law claims necessarily fail as well. In addition to that fundamental flaw, the State Law Brief explains a number of other defects in the state law claims.

ALLEGATIONS[4]

A. The Parties

Defendants are pharmaceutical companies headquartered in the United States. *See* CAC ¶¶ 169-171. Defendants research, develop, and manufacture prescription medications, including insulins. *See id*. Defendants have been at the cutting edge of innovation in insulin treatments for decades, and consistently have brought to market in the United States new insulin products representing "leap[s] forward." *See id.* ¶¶ 229-233.

The insulins at issue in this case are "analog" insulins, which are synthetic insulin products created by modifying the molecular structure of natural insulin created by the human body. *See id.* ¶ 231. Defendants' analog insulins are widely viewed as the best-in-class treatments for insulin-dependent diabetics, based on their ability to "more closely mimic the way the human body naturally absorbs insulin released by the pancreas." *Id.* ¶¶ 234-238.

[4] These allegations are assumed to be true solely for purposes of defendants' motion to dismiss. In considering a motion to dismiss, the Court may consider the materials referenced and incorporated into the complaint and matters of public record. *See, e.g.*, *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 568 n.13 (2007) ("the District Court was entitled to take notice of the full contents of the published articles referenced in the complaint"); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 166 (3d Cir. 2014) (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)); *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 623 (D.N.J. 2002) (on a motion to dismiss, a court may consider matters of public record and "may properly refer to the full text" of documents cited in the complaint).

Plaintiffs are seventy-one identified individuals with diabetes or their relatives (and one Jane Doe), who allege that they have used various analog insulins produced by defendants and have made out-of-pocket payments based on a "benchmark price." *Id.* ¶¶ 25-168.[5] Plaintiffs define the "benchmark price" as the defendants' "Wholesale Acquisition Cost" and "Average Wholesale Price." *Id.* ¶ 187. Plaintiffs bring this action on behalf of a putative class of "[a]ll individual persons in the United States . . . who paid any portion of the purchase price for a prescription of Lantus, Levemir, Novolog, Humalog, Apidra, and/or Toujeo at a price calculated by reference to a benchmark price . . . for purposes other than resale." *Id.* ¶ 279.

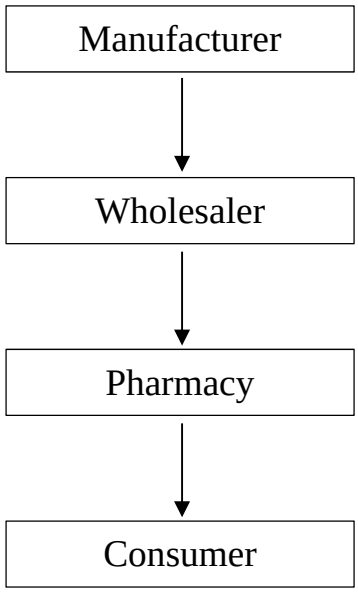
B. The Distribution of, and Payment for, Branded Prescription Drugs

The physical distribution of a branded prescription drug such as analog insulin involves three discrete transactions. *First*, a drug manufacturer sells its medication to a wholesaler. *Id.* ¶¶ 176-177. *Second*, the wholesaler takes possession of the medication and re-sells it to a pharmacy. *Id.* ¶¶ 177, 183 fig. 3.

[5] Three plaintiffs allege that they currently use prior-generation insulins known as "human insulins." *See* CAC ¶¶ 88, 128, 150. Human insulins sell for a fraction of the cost of analog insulins and are safe alternatives for many consumers. *Id.* ¶¶ 233 tab. 2, 237.

Third, the pharmacy sells the medication to consumers. *Id.* ¶¶ 179, 180, 183 fig. 3; *Follow the Pill* at 9-10.[6]

Figure 1
The Physical Path of a Prescription Drug



Health insurers and PBMs, which many insurers hire to manage their prescription drug benefits, are not directly involved in this distribution chain because they do not take physical possession of the medication. CAC ¶¶ 178-179.

[6] "*Follow the Pill*" refers to The Health Strategies Consultancy LLC, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, Kaiser Family Foundation (Mar. 2005) (incorporated by reference by CAC ¶ 179 n.19).

The appendix to this brief includes relevant excerpts of the materials incorporated by reference in the complaint that are cited in this brief, as well as excerpts of certain materials in the public record also cited in it. *See* Defendants' Appendix of Materials Referenced in Consolidated Amended Class Action Complaint and Materials in the Public Record.

Three separate payments are associated with these transactions: (1) from the wholesaler to the manufacturer; (2) from the pharmacy to the wholesaler; and (3) from the consumer—and her insurer, if any—to the pharmacy. *Id.* ¶ 181. In addition to these transactions, there frequently is an additional payment outside the distribution chain: the payment of a rebate from the manufacturer to the insurer or the insurer's PBM. *Id.* ¶ 182. The nature of these payments, and the manner in which they are determined, are described below.

Payments from Wholesalers to Manufacturers. Wholesalers pay manufacturers based on the publicly reported list price established by the manufacturer, which is known as the Wholesale Acquisition Cost ("WAC"). *Id.* ¶ 18. WAC is defined by federal statute. It is "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . . ." 42 U.S.C. § 1395w-3a(c)(6)(B).

Consistent with the statutory definition, wholesalers pay the manufacturer WAC minus small percentage discounts that they can earn for prompt payment and meeting other incentives. CAC ¶¶ 181, 186; *Nat'l Ass'n of Chain Drug Stores v. New England Carpenters Health Benefits Fund*, 582 F.3d 30, 36 (1st Cir. 2009);

Pricing and Reimbursement at 8.[7] Manufacturers report the WAC for their drugs to third-party publishers, which publish the WAC in publicly available drug-pricing compendia.[8] Plaintiffs refer to WAC as a "benchmark price."[9]

Payments from Pharmacies to Wholesalers. Wholesalers sell to pharmacies at a price they negotiate with each pharmacy. CAC ¶ 183 & fig. 3. In practice, wholesalers are able to negotiate a small percentage markup over what they paid to the manufacturer. *See id.* ¶ 13; *Pricing and Reimbursement* at 8. Thus, WAC is frequently very close to the prices paid by pharmacies. CAC ¶ 186; *Prescription Drug Pricing* at 3.[10] The average prices paid by pharmacies are

[7] "*Pricing and Reimbursement*" refers to Ernst R. Berndt & Joseph Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets*, at 15 (Harvard Kennedy School, National Bureau of Economic Research, Sept. 2010) (incorporated by reference by CAC ¶ 176 n.11).

[8] In addition, manufacturers are required to report to the federal government the average price that wholesalers pay for each drug after accounting for any discounts earned by the wholesalers, which is called Average Manufacturer Price ("AMP"). 42 U.S.C. §§ 1396r-8(b)(3)(A), 1396r-8(k)(1).

[9] Plaintiffs also use "benchmark price" to refer to the Average Wholesale Price ("AWP"), which is mathematically related to WAC. CAC ¶ 187; *see also Pricing and Reimbursement* at 20 (AWP is typically determined by publishers of pricing compendia, which set AWP at a fixed percentage markup over the WAC reported by manufacturers).

[10] "*Prescription Drug Pricing*" refers to Congressional Budget Office, *Prescription Drug Pricing in the Private Sector* (Jan. 2007) (incorporated by reference by CAC ¶ 209 n.30); *see also* CAC ¶ 187.

publicly available: The federal government publishes the average price for most prescription drugs on the internet on a weekly basis.[11]

Payments from Consumers and Their Insurers to Pharmacies. Drug manufacturers such as defendants do not set the price that a consumer pays for a prescription medication. Rather, the consumer's payment is determined by her pharmacy and by insurance benefit design. CAC ¶¶ 192-208. If a consumer is *uninsured*, then the pharmacy unilaterally determines the price the consumer must pay; different pharmacies can charge different prices for the same medication. *See id.* ¶¶ 11 n.8, 190, 280. If a consumer is *insured*, the insurer or its PBM negotiates the price with the pharmacy. *See id.* ¶¶ 179, 183 fig. 3, 184; *Prescription Drug Pricing* at 10.[12] The insurer and the consumer each pay a portion of this negotiated price, with the consumer's share determined by the terms of her insurance

[11] *See* Medicaid.gov, "Pharmacy Pricing," *available at* https://goo.gl/AZa1ZY (linking to downloadable files providing weekly National Average Drug Acquisition Cost for most drugs). The Court can take judicial notice that this pricing information is publicly available. *See, e.g.*, *Vanderklok v. United States*, 868 F.3d 189, 205 n.16 (3d Cir. 2017) (taking judicial notice of "information [that] is publicly available on government websites").

[12] *See also* 42 C.F.R. §§ 423.104(d), (e), (f)(1), (g)(1) (requiring Medicare Part D plans to provide beneficiaries with "access to negotiated prices"); *id.* § 423.100 (defining "negotiated price"); 42 U.S.C. § 1395w-114a(g)(6) (defining "negotiated price" for purposes of the Medicare coverage gap discount program). PBMs form pharmacy networks, and use their leverage to negotiate with pharmacies for discounted prices in exchange for access to their networks. *See* CAC ¶ 179 n.17 (incorporating by reference Thomas Gryta, "What Is a 'Pharmacy Benefit Manager?,'" WALL ST. J., July 21, 2011).

coverage—namely, the deductible, copayment, or coinsurance requirements. *See, e.g.*, CAC ¶¶ 11, 181, 192. In many cases, the consumer pays a fixed copayment and the insurer pays the remainder of the negotiated price. *See id.* ¶¶ 192, 202, 207. However, plaintiffs allege that consumers who have not met their deductible pay the full negotiated price, with no contribution from the insurer. Similarly, they allege that consumers subject to a coinsurance requirement pay a specified percentage of the negotiated price. *See id.* ¶¶ 190, 193, 203.

Plaintiffs allege that the prices charged by pharmacies to uninsured consumers and the prices set by insurers and PBMs for consumers subject to deductible and coinsurance requirements are based on the benchmark price. *See id*. ¶¶ 184, 209-210.[13] Plaintiffs seek to represent a putative class covering these consumers. *Id*. ¶¶ 279-281.

Rebate Payments from Manufacturers to PBMs. PBMs do not purchase prescription drugs or make any payments to manufacturers. *See id.* ¶¶ 178-179. Rather, acting on behalf of insurers, PBMs negotiate discounts—in the form of rebates—from manufacturers. *Id.* ¶¶ 181, 183 fig. 3, 209. Plaintiffs allege that some portion of these rebate payments are retained by the PBMs, but "a large portion" are passed on to insurers. *See id.* ¶¶ 10, 185. These rebates "effectively

[13] This includes coinsurance payments by consumers in Medicare Part D's so-called "Donut Hole." CAC ¶¶ 190, 208.

lower the cost paid for the product by the plan sponsor" and "lower the sponsor's cost of providing the benefit." *J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc.*, 2005 WL 1396940, at *9 (S.D. Ohio June 13, 2005). According to plaintiffs, however, some insurers have elected not to pass on manufacturer rebates to consumers who pay for prescription drugs during the deductible or coinsurance periods of their health insurance plans. *See, e.g.*, CAC ¶ 20. Whether and how the insurer passes through the rebate to these consumers depends on the terms of the consumer's insurance policy. *Id.* ¶ 211.

Plaintiffs contend that the "benchmark prices" that defendants have reported for their insulin products are "fraudulent" because they do not account for manufacturer rebate payments to PBMs. *Id.* ¶¶ 11, 16. This conflates two unrelated sets of transactions involving different entities. The "benchmark prices" (WAC and AWP) relate to the prices paid by wholesalers and pharmacies to acquire a drug. Separately, manufacturers pay rebates to PBMs—who negotiate for them on behalf of insurers—to help secure favorable formulary placement. The rebate to the *PBM* does not reduce or offset the amounts that the *wholesaler and pharmacy* already have paid.

A simple example based on prices from the complaint illustrates this point. *See id.* ¶ 210. Imagine that, based on the benchmark price set by the manufacturer, the wholesaler pays $367.50 to the manufacturer for analog insulin and the

pharmacy then pays $375.00 to the wholesaler. Assume further that the PBM has negotiated a price of $382.50 with the pharmacy. The pharmacy collects a $30.00 copayment from the consumer and $352.50 from the PBM (on the insurer's behalf). Pursuant to a separately negotiated agreement, the manufacturer later pays a $150.00 rebate to the PBM. The rebate reduces the manufacturer's net revenue to $217.50 ($367.50 – $150.00) and the PBM's net cost to $202.50 ($352.50 – $150.00), but it does not change the prices paid by the wholesaler ($367.50) and pharmacy ($375.00).

C. Manufacturer-PBM Rebate Negotiations

Plaintiffs assert that PBM rebate payments are part of a scheme to inflate the price of analog insulin, but their specific allegations make clear that the rebates are simply a form of "negotiate[d] price discounts." *Id.* ¶ 8.

According to plaintiffs, the three largest PBMs (CVS Health, Express Scripts, and OptumRx) "aggregat[e] the business of multiple insurers" and collectively "control over 80% of the PBM market, covering 180 million insured lives." *Id.* ¶¶ 7-8. Armed with this market power, the PBMs create formularies—ranked lists of drugs—that their insurers rely on "to determine how much of their members' drug costs they will cover." *Id.* ¶ 8. Plaintiffs allege that "[h]ealth insurers cover all or a portion of their members' drug costs based on whether and where drugs fall on their PBMs' formularies." *Id.* ¶ 188. If a drug is excluded

from these formularies or placed in a less-favored reimbursement tier on the formulary, consumers may be required to pay the full cost of the medication or a larger share of the cost (through higher copayments or coinsurance percentages). *Id.* ¶¶ 8-9, 188, 202-203. That, in turn, will reduce demand for, and use of, the drug. *Id.* ¶¶ 8-9, 188. The use of formularies thus gives the PBMs enormous "power" to extract rebates from manufacturers. *Id.*; *see also id.* ¶ 247 ("PBMs control the formularies that determine whether people living with diabetes will purchase Novo Nordisk, Eli Lilly, or Sanofi's drugs.").

The PBMs' power to negotiate rebates from drug manufacturers is especially pronounced in the case of analog insulin. Analog insulins are "in the same therapeutic class and are perceived to have similar effectiveness and risk profile" (CAC ¶ 212), giving PBMs the power to exclude a more expensive analog insulin from a formulary in favor of a less expensive one. *See id.* ¶ 9; *Prescription Drug Coverage* at 104 ("Manufacturers of brand-name drugs that treat conditions for which an alternative brand-name treatment is available . . . have a strong incentive to grant discounts to the PBM in return for the inclusion of their drugs in the formulary.").[14] Plaintiffs allege that as a result, Novo Nordisk, Lilly, and Sanofi

[14] "*Prescription Drug Coverage*" refers to U.S. Dep't of Health and Human Servs., *Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices* (Apr. 1, 2000) (incorporated by reference by CAC ¶ 186 n.23); *see also Prescription Drug Pricing* at 12 ("[I]n negotiating with a
(….continued)

aggressively compete against each other by offering rebates to PBMs for formulary placement. *See* CAC ¶¶ 188, 247.[15]

Plaintiffs characterize the rebates defendants pay to the PBMs as illegal "kickbacks" (*see* CAC ¶¶ 16, 216), but the federal government expressly exempts such rebate payments to PBMs from the federal Anti-Kickback Statute. *See* 42 C.F.R. § 100.952 (2017); *see also* 68 Fed. Reg. 23731 (May 5, 2003) (explaining that the anti-kickback safe harbor protects "rebates or other payments by drug manufacturers to PBMs"). Further, federal and state governments have long relied on rebate payments to reduce their own expenditures on branded drugs. *See, e.g.*, 42 U.S.C. § 1396r-8(a) (2016) (requiring manufacturers, since the 1990s, to pay rebates to the Medicaid program as a condition of providing insurance coverage for the manufacturer's medications); Patient Protection and Affordable Care Act, Pub. L. 111-148, § 2501(c), 124 Stat. 119 (2010) (substantially increasing the amount of Medicaid rebates that manufacturers must pay); *Pharm. Research & Mfrs. of Am.*

(continued….)
manufacturer, the PBM has the greatest leverage for brand-name drugs with close substitutes available on the market.").

[15] *See also* Allison Tsai, *The Rising Cost of Insulin* at 2, Diabetes Forecast (Mar. 2016) (manufacturers "offer [PBMs] big discounts" to "better position their drug against competitors — so their drug ends up on a lower tier while their competitor's is on a higher tier with higher copays") (incorporated by reference by CAC ¶ 183 n.22).

v. Walsh, 538 U.S. 644, 649 (2003) (describing how states negotiate "supplemental" Medicaid rebate agreements with manufacturers).

Although manufacturer rebates have been a fixture of the U.S. pharmaceutical industry for decades,[16] plaintiffs accuse defendants of "refus[ing] to disclose" the specific rebates paid to the PBMs for analog insulin. CAC ¶ 13.[17] The amounts of the rebates paid by manufacturers to PBMs for specific drugs are subject to strict confidentiality agreements. *See, e.g., id*. Moreover, the Federal

[16] *See, e.g.*, Robert F. Atlas, *The Role of PBMs in Implementing the Medicare Prescription Drug Benefit*, 23 Health Affairs w4-504, w4-507 (July 2004) (incorporated by reference by CAC ¶ 188 n.24); *Follow the Pill*, *passim*; *Prescription Drug Pricing*, *passim*.

[17] Any suggestion that manufacturers hid the fact that they pay rebates to PBMs, or that such rebates have been substantial and growing along with list price increases, is belied by public disclosures of which the Court can take judicial notice. *See, e.g.*, Novo Nordisk, Annual Report 2015, at 64 (Feb. 2, 2016); Novo Nordisk's (NVO) CEO Lars Rebien Sorensen on Q4 2015 Results—Earnings Call Transcript, Seeking Alpha (Feb. 3, 2016); Novo Nordisk, Annual Report 2014, at 23, 63-64 (Jan. 29, 2015); Novo Nordisk, Annual Report 2013, at 32, 42, 64 (Jan. 29, 2014); Sanofi 2016 Annual Report at 9 (noting increased Lantus rebates "in order to maintain favorable formulary positions"); Sanofi 2015 Annual Report at 8 (same); Lilly, 2016 Annual Report at F7, F12; Lilly, 2015 Annual Report at F7, F12; Lilly 2016 Integrated Summary Report at 1 ("The increase in discounts on Lilly sales creates a gap between list prices for our medications and the actual prices realized by Lilly."). On a motion to dismiss, the Court may take judicial notice of such publicly disclosed information. *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 401 n.15 (3d Cir. 2006) (affirming decision to take judicial notice of newspaper articles "to indicate what was in the public realm at the time"); *see also Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) ("SEC filings are . . . matters of public record of which the court can take judicial notice").

Trade Commission ("FTC") has openly criticized legislative proposals to require public disclosure of manufacturer rebates. As the FTC concluded, the required disclosure of aggregate rebates paid to the PBMs would increase the risk that manufacturers would not compete aggressively through rebates, and "may lead to higher prices for PBM services and pharmaceuticals."[18]

D. The Alleged "Scheme"

Plaintiffs argue that defendants have raised the "benchmark" prices of their analog insulins "in an astounding and unjustifiable manner." CAC ¶¶ 2, 6. Plaintiffs attribute these price increases to "purported 'rebate' schemes" between each defendant and the three largest PBMs (CVS Health, Express Scripts, and OptumRx). *Id.* ¶¶ 6-7.

Plaintiffs accuse defendants of increasing their benchmark prices while holding their "real" prices constant (through correspondingly increased rebates) in order to increase the "spread" (which, according to plaintiffs, is the difference between "the benchmark price and the real price") offered to PBMs. *Id.* ¶¶ 6, 213. According to plaintiffs, higher spreads are attractive to PBMs because "[t]he larger the spread between a drug's benchmark and real price, the greater the headroom for the PBM to earn money on that drug." *Id.* ¶ 10; *see also id.* ¶ 306 ("[H]igher

[18] Susan A. Creighton, *et al.*, Federal Trade Commission, Letter to Assembly Member Greg Agharzarian, at 4, 9 (Sept. 7, 2004), *available at* https://goo.gl/z8R6j5.

spreads result in increased profits for PBMs."). Thus, manufacturers such as defendants allegedly have an "incentive" to offer a larger spread to PBMs than those offered by their competitors because they "'don't want their products disadvantaged.'" *Id.* ¶ 214 (quoting *Net Pricing Trends* at 1).[19]

Although plaintiffs characterize this as an illegal "scheme," they do not allege that it is unlawful for defendants to raise the publicly reported benchmark prices for their insulin products. Nor do they allege that it is unlawful for defendants to offer substantial rebates to PBMs and their insurer clients for insulin. Instead, plaintiffs assert that the combination of these actions is somehow "fraudulent" because "the 'rebates' drug manufacturers offer PBMs are not reflected in th[e] prices" paid by consumers at the pharmacy counter. *Id.* ¶ 11; *see also id.* ¶¶ 6, 209, 318. But plaintiffs do not identify a single instance in which a defendant represented that its "benchmark prices" for insulin accounted for PBM rebates. Nor do they allege any facts showing that consumers were under the impression that the prices they paid for insulin at the pharmacy reflected the rebates defendants paid to the PBMs.

[19] "*Net Pricing Trends*" refers to Richard Evans, Scott Hinds & Ryan Baum, *US Rx Net Pricing Trends Thru 2Q16*, SSR LLC (Oct. 5, 2016) (incorporated by reference by CAC ¶ 214 n.32).

Plaintiffs' allegations of fraud boil down to the contention that the price they paid for insulin at the pharmacy should have been directly and fully offset by the rebates that the defendant manufacturers paid to their PBMs. *See, e.g.*, *id.* ¶ 6 ("[C]onsumers do not see these lower prices because when they make their contribution—for example, as cash payers, or when making co-insurance payments, at the pharmacy point-of-sale—the transaction is based on the *benchmark* price . . ."). [20] Defendants have no control, however, over whether or how a PBM or health insurer passes through the rebate to the insured consumers. Instead, the amount an insured consumer pays for insulin during deductible or coinsurance periods depends on the terms of the consumer's insurance policy. *Id.* ¶¶ 8, 11, 188, 190, 193, 203, 204.

Plaintiffs nevertheless allege that Novo Nordisk, Sanofi, and Lilly each formed a distinct "association-in-fact" enterprise with the three largest PBMs. Each "enterprise" allegedly engaged in "a fraudulent payoff scheme" to "exchang[e] kickbacks . . . for preferred formulary positions" for a defendant's insulin products. *See id.* ¶¶ 295, 336, 377. Plaintiffs argue that each of the alleged

[20] This is actually a generous interpretation of plaintiffs' position. Plaintiffs apparently believe not only that insured consumers should have received rebated amounts at the point of sale, but that uninsured consumers—who by definition do not have health insurers and PBMs negotiating on their behalf, and whose purchases thus do not trigger the payment of rebates—should have received lower point-of-sale pricing too.

schemes entails a "pattern" of predicate acts of federal mail and wire fraud in violation of 18 U.S.C. §§ 1341 and 1343. *See id.* ¶¶ 312-317, 353-358, 394-399. Plaintiffs allege in conclusory fashion that the asserted RICO violations "have directly and proximately caused plaintiffs and class members to be injured . . . because plaintiffs and class members have paid inflated out-of-pocket expenses" for insulin. *Id.* ¶¶ 324, 365, 406.

LEGAL STANDARDS

A. Rule 8(a)

A complaint should be dismissed if, assuming its well-pleaded allegations of fact are true, it fails to plausibly show that the plaintiff is entitled to relief. *See, e.g.*, *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). Legal conclusions and other conclusory allegations, however, are not assumed to be true. *Id.* at 678.

B. Rule 9(b)

In addition, claims sounding in fraud must be pleaded with the particularity required by Rule 9(b), including identification of "specific fraudulent statements, omissions, or misrepresentations." *Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 85-86 (3d Cir. 2015). The allegations must be specific enough not only to put "defendants on notice of the precise misconduct with which they are charged," but also—and more importantly—"to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Lum v. Bank of Am.*, 361

F.3d 217, 223-24 (3d Cir. 2004), *abrogated on other grounds as recognized by In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 323 n.22 (3d Cir. 2010).

C. RICO Claims

Congress enacted RICO as part of the Organized Crime Control Act of 1970 "for the purpose of seek[ing] the eradication of organized crime in the United States." *Beck v. Prupis*, 529 U.S. 494, 496 (2000) (internal quotation marks and citation omitted). RICO targets criminal activity, including conduct that is "indictable" as federal mail or wire fraud. 18 U.S.C. § 1961(1)(B) (2012) (citing federal criminal statutes including 18 U.S.C. §§ 1341 & 1343); *see, e.g., Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 647 (2008). Thus, a prerequisite for any civil liability under RICO claims premised on mail and wire fraud, like plaintiffs' claims, is that the defendants engaged in deceptive conduct *with the specific intent to defraud*. *See, e.g., Advanced Oral Techs., L.L.C. v. Nutres Research, Inc.*, 2011 WL 198029, at *8 (D.N.J. Jan. 20, 2011).

"[A]ll too frequently," however, civil RICO plaintiffs "attempt to mold their claims to the RICO form even though their injuries do not fall within those intended to be addressed by the [statute]." *Rosenson v. Mordowitz*, 2012 WL 3631308, at *4 (S.D.N.Y. Aug. 23, 2012). "'[E]xperience reveals that many plaintiffs, rather than fostering RICO's mission as private attorneys general aiding public law enforcement, actually appear as private prospectors digging for RICO's

elusive gold, and more often than not generating substantial costs rather than net gains to the public.'" *Id.* (quoting *Gross v. Waywell*, 628 F. Supp. 2d 475, 481 (S.D.N.Y. 2009)). Complaints that successfully plead a bona fide claim under RICO are "rare." *Id.* at *5; *see also Gross*, 628 F. Supp. 2d at 479-80, 495 ("the incidence of favorable judgments for RICO plaintiffs is . . . stunningly awful" (internal quotation marks omitted)).

This backdrop makes clear why civil RICO claims are among the most difficult claims to plead. *See, e.g.*, *Rogers v. Morrice*, 2013 WL 1750004, at *6 (D.N.J. Apr. 23, 2013) ("fraud and civil RICO claims are subject to demanding pleading standards"). "Because the mere assertion of a RICO claim . . . has an almost inevitable stigmatizing effect on those named as defendants, . . . courts should strive to flush out frivolous RICO allegations at an early stage of the litigation." *Grant v. Turner*, 2010 WL 4004719, at *3 (D.N.J. Oct. 12, 2010); *see also Katzman v. Victoria's Secret Catalogue*, 167 F.R.D. 649, 655 (S.D.N.Y. 1996) ("Civil RICO is an unusually potent weapon—the litigation equivalent of a thermonuclear device." (citation omitted)), *aff'd*, 113 F.3d 1229 (2d Cir. 1997). This is especially true of RICO claims premised on mail or wire fraud, which "must be particularly scrutinized because of the relative ease with which a plaintiff may mold a RICO pattern from allegations that, upon closer scrutiny, do not

support it." *Kolar v. Preferred Real Estate Invs., Inc.*, 361 F. App'x 354, 363 (3d Cir. 2010) (quotation omitted).

To state a civil RICO claim, plaintiffs must plead particularized facts that plausibly show (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity. *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985). In addition, plaintiffs must allege that they have suffered a cognizable injury to their business or property, and that their injury was caused "by reason of" a violation of RICO. 18 U.S.C. § 1964(c) (2012); *see, e.g., In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 246 (3d Cir. 2012). The RICO violation must be *both* a "but-for" *and* a proximate cause of the plaintiff's injury. *See Bridge*, 553 U.S. at 654. To plead proximate causation, a complaint must demonstrate a "'direct relation between the injury asserted and the injurious conduct alleged.'" *Id.* (quoting *Holmes v. Secs. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992)).

D. NJCFA Claims

To state a claim under the NJCFA, a plaintiff must show (1) unlawful conduct by the defendant, (2) an "ascertainable loss" by the plaintiff, and (3) a causal relationship between the unlawful conduct and the ascertainable loss. *See DeGennaro v. Am. Bankers Ins. Co. of Fla.*, 2017 WL 2693881, at *6 (D.N.J. June 22, 2017) (Martinotti, J.). Where, as here, plaintiffs' allegations sound in fraud,

claims under the NJCFA are subject to Rule 9(b)'s heightened pleading standard. *Id.* at *5.

ARGUMENT

As set forth in greater detail below, plaintiffs' RICO claims fail for a number of reasons.

First, plaintiffs lack statutory standing to assert any RICO claims because they are "indirect purchasers" who do not purchase analog insulin directly from any defendant. This indisputable fact alone disposes of plaintiffs' RICO claims.

Second, even if plaintiffs had standing, they have not alleged the most basic element of a RICO claim: the existence of a predicate act. Plaintiffs assert violations of the criminal mail and wire fraud statutes, but the complaint does not allege a single instance in which a defendant misrepresented its prices or withheld information that it had a duty to disclose—much less that any defendant specifically intended to defraud consumers (or anyone else). The mere fact that some consumers pay a relatively higher price for insulin because they do not receive the benefit of rebates paid to PBMs cannot plausibly support a claim of criminal fraud.

Third, plaintiffs fail to plead the existence of a RICO enterprise. The complaint is devoid of plausible allegations that defendants formed *any* kind of enterprise or participated in conducting any such enterprise. At most, the

complaint describes a classic "hub-and-spoke" arrangement in which a common defendant (each manufacturer) supposedly committed acts of fraud with the aid of different entities (the PBMs). Such rimless "hub-and-spoke" allegations fail as a matter of law to support a RICO claim. Plaintiffs also fail to allege other essential elements of a RICO enterprise: a common purpose among the defendants and the PBMs, and the participation of the defendants in conducting the affairs of the alleged enterprise.

Fourth, plaintiffs fail to plead that any purported misrepresentation or omission proximately caused *any* injury to plaintiffs. Even if defendants had fully disclosed the amount of rebates paid to the PBMs for insulin, it would not have changed the amounts that plaintiffs paid for insulin. The prices paid by plaintiffs are dictated by pharmacies and their own insurers, not by defendants.

The NJCFA claims fail for similar reasons. Plaintiffs cannot state a NJCFA claim because they do not allege with the required specificity how defendants violated the statute, when and where any purported misrepresentations were made, or who made any such statements. Plaintiffs also fail to allege that they suffered the "ascertainable loss" necessary to state a NJCFA claim. Although plaintiffs claim that defendants' scheme "inflated" the price of insulin, courts have rejected attempts to rely on a price inflation theory to establish a claim under the NJCFA.

I. The RICO Claims Should Be Dismissed

A. Plaintiffs' Claims Are Barred by the Indirect Purchaser Rule

Plaintiffs lack RICO standing because they are not the first party in the distribution chain who pay for insulin based on the "benchmark price." Plaintiffs' core allegation is that defendants each engaged in a "scheme" to "inflate the benchmark prices of rapid- and long-acting analog insulin drugs." CAC ¶ 24. Plaintiffs acknowledge, however, that consumers are not the first party (or even the second) to pay for analog insulin based on the purportedly inflated benchmark price. Instead, defendants' analog insulins are sold to wholesalers at prices based on WAC, which in turn sell them to pharmacies, hospitals, and clinics at prices that approximate WAC. *See id.* ¶ 177; *Pricing and Reimbursement* at 8; *Follow the Pill* at 18; *Prescription Drug Pricing* at 3.[21] Because plaintiffs are three levels down the distribution chain from defendants, they are classic "indirect purchasers" who lack standing under RICO. *See McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 848, 855 (3d Cir. 1996) ("only the purchaser immediately downstream" has standing to assert RICO claims for payment of "excessive prices").

The indirect purchaser rule originated in the antitrust context. In *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977) and *Kansas v. UtiliCorp United Inc.*, 497

[21] *See also* CAC ¶ 187 (explaining that "a drug's benchmark price" refers to "its Average Wholesale Price (AWP) or the mathematically-related, Wholesale Acquisition Price (WAC)").

U.S. 199 (1998), the Supreme Court established a bright-line rule that *only* the immediate purchaser has standing to sue a manufacturer for violations of federal antitrust laws. Any other approach would pose "the risk of duplicative recovery and the potential for overly-complex damages and apportionment calculations." *McCarthy*, 80 F.3d at 851 n.14. Because RICO's private cause of action, 18 U.S.C. § 1964(c), was modeled on the Clayton Act, "antitrust standing principles apply equally to allegations of RICO violations." *Id.* at 855. Accordingly, the Third Circuit has held that the "precepts taught by *Illinois Brick* and *Utilicorp* apply to RICO claims, thereby denying RICO standing to indirect victims." *Id.*; *see also, e.g.*, *Hale v. Stryker Orthopaedics*, 2009 WL 321579, at *3 (D.N.J. Feb. 9, 2009) ("The Third Circuit has extended application of the 'direct purchaser' standing rule to RICO claims.").

The bright-line indirect purchaser rule is an insurmountable obstacle to plaintiffs' RICO claims. Plaintiffs do not, and cannot, allege that they purchase analog insulin directly from any defendant; instead, their allegations confirm that defendants' products are sold "from manufacturer to wholesaler, wholesaler to retailer (or mail order), and retailer to patient." CAC ¶ 180; *see also id.* ¶¶ 18, 176-177, 181, 186. And plaintiffs allege that both wholesalers and retailers pay prices based on the allegedly inflated "benchmark prices" *before* plaintiffs

purchased insulin from pharmacies. *See id.* ¶¶ 313, 354, 395 (alleging that "the distribution chain" relies on "benchmark prices").

Accordingly, the indirect purchaser rule requires dismissal of plaintiffs' RICO claims, "even if the majority of the injury is borne by [consumers]." *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 94 (3d Cir. 2011); *see also McCarthy*, 80 F.3d at 849 (indirect purchaser rule applies even if "the full cost of the product (and hence one hundred percent of any overcharge) had been passed on"); *Link v. Mercedes-Benz of N. Am., Inc.*, 788 F.2d 918, 930 (3d Cir. 1986) (indirect purchaser rule applies even if inflated prices are "passed on" and "direct purchasers" lack incentive to sue).

Hale v. Stryker Orthopaedics is directly on point. There, the plaintiffs alleged that manufacturers of artificial hip and knee implants violated RICO through a "collusive kickback scheme" that "allegedly inflated the prices charged" for patients' implants. 2009 WL 321579, at *1. Judge Martini dismissed the RICO claim because the plaintiffs did "not plead that they purchased the joints used in their knee replacement surgeries directly from [the defendants]." *Id.* at *3. The Court explained that "[b]etween [p]laintiffs and [d]efendants in the chain of distribution stand several actors, including the hospitals performing the joint surgeries and plaintiffs' insurers." *Id.* at *4. Accordingly, "[p]laintiffs' co-

payment alone does not allow them to stand in the shoes of a direct purchaser for standing purposes." *Id.*

The same is true here. Any putative injury to plaintiffs necessarily first passed through the intermediary entities in the distribution chain. Accordingly, plaintiffs lack standing to assert their RICO claims against defendants. *See Warren*, 643 F.3d at 91, 95 (downstream purchaser of drugs lacks standing to sue manufacturer under antitrust laws); *see also Delaware Valley Surgical Supply Inc. v. Johnson & Johnson*, 523 F.3d 1116, 1122 (9th Cir. 2008) (downstream purchaser of medical products lacked standing under the "sensible and straightforward" and "bright line rule" set forth in *Illinois Brick*); *In re Brand Name Prescription Drugs Antitrust Litig.*, 248 F.3d 668, 670 (7th Cir. 2001) (consumers who "had not purchased . . . drugs directly from the defendants" would lack standing to assert federal antitrust claims).

B. Plaintiffs Do Not Plead Facts Amounting to Mail or Wire Fraud

Plaintiffs fail to plead the existence of any "fraudulent misrepresentation or omission reasonably calculated to deceive persons of ordinary prudence and comprehension," *Lum*, 361 F.3d at 223 (internal citation omitted), much less with the particularity required by Rule 9(b), *see Cephalon*, 620 F. App'x at 85-86. Absent "a specific fraudulent statement," identified by "the time, place, speaker and [its] content," a civil RICO claim grounded in fraud should be dismissed. *Jaye*

v. Oak Knoll Vill. Condo. Owners Ass'n, Inc., 2016 WL 7013468, at *15 (D.N.J. Nov. 30, 2016).

Plaintiffs accuse each defendant of having made "false or incomplete statements intended to mislead health care payers and consumers" concerning benchmark prices and the "existence, amount, and purpose of . . . rebates." CAC ¶¶ 318, 359, 400. These allegations are based on two theories. *First*, plaintiffs allege that the benchmark price defendants charge to wholesalers is "false and misleading" because it fails to account for the rebates paid to the PBMs. *Id.*; *see also id.* ¶¶ 6, 11, 209, 300. *Second*, plaintiffs allege that defendants engaged in fraudulent omissions by failing to disclose to the public "the existence and amount of steep rebates" that are provided "to the PBMs in exchange for preferred formulary positions." *Id.* ¶¶ 297, 338, 379. As shown below, neither of these allegations is sufficient to state a plausible predicate act of mail or wire fraud.

1. <u>The Complaint Fails to Allege a Misrepresentation</u>

Plaintiffs' RICO claims fail to allege a misrepresentation by defendants with the specificity required by Rule 9(b) or otherwise. Plaintiffs assert that defendants have increased the "spread" between their benchmark prices and "the real price arranged between the manufacturers and the PBMs." *Id.* ¶ 6. But allegedly excessive pricing is not fraudulent. *See, e.g.*, *Eike v. Allergan*, 850 F.3d 315, 318 (7th Cir. 2017) (en banc) ("The fact that a seller does not sell the product that you

want, or at the price you'd like to pay, is not an actionable injury."). Even charging different prices to consumers for prescription medications is not unlawful. *See Langford v. Rite Aid of Alabama, Inc.*, 231 F.3d 1308, 1313-14 (11th Cir. 2000) (dismissing RICO claim based on allegations that pharmacy "charged plaintiffs more for their prescription medication than it charged other consumers" because "variable pricing is the norm in many industries"); *Bonilla v. Volvo Car Corp.*, 150 F.3d 62, 71 (1st Cir. 1998) ("price disparity is not itself fraud" because "nothing in the law of fraud [] prevents even a single seller from charging different markups").

No doubt aware of this fundamental problem with their claims, plaintiffs try to manufacture an argument that defendants misrepresented that their "benchmark prices" reflect rebates that they pay to PBMs. *See* CAC ¶ 11 ("rebates drug manufacturers offer PBMs are not reflected in these prices"). As shown below, however, plaintiffs offer no well-pleaded allegations to support that contention.

First, plaintiffs fail to identify—anywhere in their 200-page complaint—a single instance in which defendants represented that the benchmark prices reflected rebates paid to PBMs. To the contrary, the specific statements in the complaint attributed to defendants expressly represent that there is a *difference* between defendants' benchmark price and the net price that defendants receive after the payment of PBM rebates. *See, e.g.*, CAC ¶ 249 (quoting Novo Nordisk statement

emphasizing that focusing on increases in its list prices is "misleading" because the "net price" Novo Nordisk realizes after "rebates, fees and other price concessions we provide to the payer . . . more closely reflects our actual profits"); *id.* ¶ 250 (quoting Lilly statement explaining that "higher rebates" demanded by PBMs result in increases in "benchmark prices without a corresponding increase in net price"); *id.* ¶ 251 (quoting Sanofi statement explaining that the company had "increased the level of rebates granted for Lantus® in order to maintain favorable formulary positions with key payers"); *see also supra* at 16 n.17 (identifying examples of defendants' public rebate disclosures).

Second, having failed to identify any actual misstatements, plaintiffs are left arguing that defendants' "benchmark prices" are themselves fraudulent misrepresentations. CAC ¶¶ 308, 349, 390. Plaintiffs' position appears to be that the "benchmark prices" were generally understood to mean a "real" or "net" price realized by the manufacturer after paying rebates to PBMs. *Id.* Plaintiffs do not offer a single allegation that would support that claim. Indeed, any such understanding would be *directly contrary to federal law*, which defines WAC as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or reductions in price*." 42 U.S.C. § 1395w-3a(c)(6)(B) (emphasis added).

Moreover, plaintiffs' assertion that WAC was understood to be a price net of PBM rebates defies common sense. WAC relates to prices paid by *wholesalers* and *pharmacies* that purchase and re-sell prescription drugs as part of the physical distribution chain. *See id.*; *see also supra* at 8-9. By contrast, rebates are paid separately and subsequently to PBMs and do not reduce or offset the amounts that the wholesaler and pharmacy already paid. *See supra* at 12-13.[22]

The Third Circuit has dismissed analogous allegations of fraud. *See Lum*, 361 F.3d at 223. In *Lum*, the plaintiffs argued that the term "'prime rate' [was] so generally understood to mean the lowest rate available to a bank's most creditworthy borrowers that the failure to disclose that some borrowers obtain loans with interest rates below the prime rate constitutes fraud." *Id.* at 226. The court rejected the argument, finding that the "the term 'prime rate' is sufficiently indefinite that it is reasonable for the parties to have different understandings of its meaning," and holding that the plaintiffs' RICO claim boiled down to a

[22] Likewise, plaintiffs do not allege any facts suggesting that AWP was defined or understood to be a price net of rebates to PBMs. Indeed, counsel for the putative class are well aware that AWP and WAC are not understood to reflect PBM rebates. More than fifteen years ago, they brought a nationwide class action alleging that these benchmark prices should reflect the price paid by *pharmacies*, not PBMs. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 65 (D. Mass. 2003) (case brought by Hagens Berman alleging that "providers like pharmacies and doctors" acquire drugs "at prices far below AWP and WAC," but "defendant manufacturers send publishers their AWPs (or their WACs) knowing that [health insurers] consider them indicators of prices to providers").

"disagreement about the meaning" of that term, but that such a disagreement "does not rise to the level of fraud." *Id.* Even more clearly here, plaintiffs' arguments about what "benchmark prices" supposedly represent do not support their accusation of criminal fraud.

2. The Complaint Fails to Allege Any Omission in Violation of a Duty to Disclose

Plaintiffs' allegations of fraudulent omissions fare no better. Mail or wire fraud can be premised on non-disclosure only when the defendant has a duty to disclose. *See, e.g.*, *United States v. Ciavarella*, 716 F.3d 705, 728-29 (3d Cir. 2013). Here, plaintiffs criticize defendants for "refus[ing] to disclose" the "real prices they offer PBMs." CAC ¶ 13. Plaintiffs also allege that defendants "concea[l] . . . the existence and amount of steep rebates" provided "to the PBMs in exchange for preferred formulary positions." *Id.* ¶¶ 297, 338, 379. But defendants were under no legal obligation to disclose either the rebates they pay to PBMs or the net prices they realize after paying rebates.[23]

It is a "settled premise that a seller generally has no duty to disclose internal pricing policies or its method for valuing what it sells." *Eller v. EquiTrust Life Ins. Co.*, 778 F.3d 1089, 1092-93 (9th Cir. 2015) (collecting cases); *see also, e.g.*, *Langford*, 231 F.3d at 1313 ("As a general matter of federal law, retailers are under

[23] While defendants were under no duty to disclose, they in fact *did* disclose the PBMs' demands for increasingly steep rebates. *See supra* at 16 n.17.

no obligation to disclose their pricing structure to consumers."). In *Langford*, the plaintiffs asserted a civil RICO claim against a pharmacy, alleging that the pharmacy had implemented a scheme to defraud uninsured customers by charging them higher prices than insured customers. The court affirmed the dismissal of the RICO claim, reasoning that "plaintiffs have not alleged any facts that would suggest that Rite Aid was subject to a duty to disclose the fact that it charged plaintiffs more for their prescription medication than it charged other consumers." *Id.* at 1314. Likewise, here, defendants had no duty to disclose the amount of rebates paid to the PBMs. *See Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 18 (2010) (Ginsburg, J., concurring) (explaining that where defendant "would have owed no duty to disclose [its] sales to anyone," its "failure to disclose could not conceivably be deemed fraud of any kind" (citation omitted)).[24]

C. Plaintiffs Do Not Plead an Actionable RICO Enterprise

Plaintiffs plead the existence of three association-in-fact enterprises, each comprising one manufacturer and the three largest PBMs (CVS Health, OptumRx, and Express Scripts). CAC ¶¶ 295, 336, 377. Plaintiffs allege that each manufacturer and all three PBMs "share the common fraudulent purpose of

[24] The FTC opposes disclosure of manufacturer rebates to PBMs because it "may lead to higher prices for PBM services and pharmaceuticals." *See supra* at 16-17 & n.18.

providing kickbacks in exchange for an exclusive or favorable formulary position" for insulin. *Id.* ¶¶ 303, 344, 385.

Plaintiffs' enterprise allegations fail for two reasons. *First*, each alleged enterprise constitutes a rimless "hub-and-spoke" conspiracy, which the Third Circuit has deemed insufficient, as a matter of law, to satisfy RICO. *Second*, plaintiffs challenge the independent commercial behavior of the defendant manufacturers and PBMs, and thus have failed to properly allege either a "common purpose" that is the *sine qua non* of a RICO enterprise, or that defendants participated in the conduct of a RICO enterprise.

1. The Complaint Alleges a Legally Deficient Rimless "Hub and Spoke" Enterprise

An association-in-fact enterprise requires "at least three structural features: a purpose, relationships among those associated with the enterprise, and longevity sufficient to permit these associates to pursue the enterprise's purpose." *Boyle v. United States*, 556 U.S. 938, 946 (2009). A rimless hub-and-spoke enterprise—in which various parties allegedly enter into separate agreements with a common defendant, but have no connection with one another aside from the common defendant's involvement with each—inherently lacks those structural features. *See In re Ins. Brokerage*, 618 F.3d at 374-75.

As the Third Circuit has reasoned, absent a "rim" unifying the entities serving as "spokes," there is nothing to "tie [] together the various [parties]

allegedly comprising the association in fact into a single entity . . . formed for the purpose of working together—acting in concert—by means of racketeering acts." *Id*. at 374 (internal quotation marks and citation omitted). Thus, allegations of a rimless wheel enterprise "fail the basic requirement that the components function as a unit, that they be 'put together to form a whole.'" *Id.* (quoting *Boyle*, 556 U.S. at 945). If such allegations were sufficient to plead an association-in-fact enterprise, "competitors who independently engaged in similar types of transactions with the same firm could be considered associates in a common enterprise"—a result that "would contravene *Boyle*'s definition of 'enterprise.'" *Id.* at 375.

Plaintiffs' enterprise allegations exemplify a legally deficient "hub and spoke" enterprise. The complaint does not even attempt to allege any direct relationships between the PBMs in connection with the alleged enterprises, but instead asserts only that "[t]here is regular communication between [each defendant] and each of the PBMs." CAC ¶¶ 298, 339, 380. In other words, each defendant is alleged to have served as the hub for three unconnected PBM spokes. Routine business relationships between a single manufacturer and three different PBMs are "not a RICO enterprise." *Valcom, Inc. v. Vellardita*, 2014 WL 1628431, at *7 (D.N.J. Apr. 23, 2014).

2. The Complaint Fails to Plead that Each Enterprise Had a "Common Purpose" or that Defendants Participated in the Conduct of Any Such Enterprise

Plaintiffs' enterprise allegations fail for the additional reason that they do not plausibly allege either that the enterprise members share a common purpose, or that defendants participated in the "conduct" of a RICO enterprise.

First, an essential element of an association-in-fact enterprise is that its members are united in a "common purpose." *Boyle*, 556 U.S. at 948; *United States v. Turkette*, 452 U.S. 576, 583 (1981). Allegations showing that a defendant is engaged in the "normal affairs" of a business relationship cannot satisfy the "common purpose" element of a RICO enterprise. *See In re Ins. Brokerage Antitrust Litig.*, 2007 WL 1062980, at *13 (D.N.J. Apr. 5, 2007) (citation omitted).

Plaintiffs assert that members of each alleged enterprise "share the common fraudulent purpose of providing kickbacks in exchange for exclusive or favorable formulary positions" for the analog insulin manufactured by the defendant. CAC ¶¶ 303, 344, 385. But the complaint contains no well-pleaded factual allegations indicating that each manufacturer and the PBMs shared each other's interests. According to the complaint, "'PBMs demand higher rebates in exchange for including [a] drug on their preferred-drug lists.'" CAC ¶ 250 (quoting Lilly); *see also id.* ¶¶ 8-9, 188, 212. In this "exchange," it is not a *PBM's* purpose to include or favor in its formulary any particular defendant's analog insulin. Instead, each

PBM leverages its ability to "exclude, or place in a non-preferred position," more expensive medications from its formulary, in order to extract rebates. *Id.* ¶ 9; *see also id.* ¶ 188. Conversely, it is not any defendant's purpose to pay higher rebates to PBMs. Instead, each defendant offers rebates to PBMs because it is competing against other defendants for inclusion and preferred placement on PBMs' formularies. *See id.* ¶ 209.[25]

The "type of interaction" alleged by plaintiffs thus "show[s] only that" the manufacturers and PBMs "ha[ve] a commercial relationship"—involving arm's-length negotiations *against* each other—"not that they had joined together to create a distinct entity" for the purpose of improperly inflating list prices of analog insulin. *In re Aetna UCR Litig.*, 2015 WL 3970168, at *31 (D.N.J. June 30, 2015) (internal quotation marks and citation omitted) (dismissing RICO claims where "each defendant maintained an independent incentive to engage in the conduct alleged"). Such a "run-of-the-mill commercial relationship where each entity acts in its individual capacity to pursue its individual self-interest" does not amount to a RICO enterprise. *Bible v. United Student Aid Funds, Inc.*, 799 F.3d 633, 655-56

[25] *See also, e.g.*, Denise Roland & Peter Loftus, *Middlemen Fuel Insulin Price Rise*, WALL ST. J., Oct. 10, 2016 (incorporated by reference by CAC ¶ 250 n.54) ("Net prices, or what drugmakers retain after discounts, have stayed the same or fallen in the past two years as the pharmaceutical companies compete to offer ever-deeper discounts to stay on the preferred drug lists at insurers and the PBM middlemen.").

(7th Cir. 2015). Otherwise, any commercial transaction in which one party receives a payment and the other receives something of value could be deemed a criminal RICO enterprise. *See, e.g.*, *Ray v. Spirit Airlines, Inc.*, 836 F.3d 1340, 1352 n.3, 1354-55 (11th Cir. 2016) (dismissing RICO enterprise allegations where defendants "were engaged in no more than a series of legitimate commercial transactions"); *Crichton v. Golden Rule Ins. Co.*, 576 F.3d 392, 400 (7th Cir. 2009) (dismissing RICO claim because "garden-variety" business relationships are "not what RICO penalizes"); *Arthur v. Guerdon Indus., Inc.*, 827 F. Supp. 273, 279-80 (D. Del. 1993) (rejecting enterprise allegations based on mobile home manufacturer's rebates to retailers, and noting that "[t]he state of the business world often requires a manufacturer . . . to provide incentives to a retailer or buyer in order to . . . be successful in the marketplace").

Indeed, plaintiffs' argument that CVS Health, Express Scripts, and OptumRX share a "common purpose" with each defendant to disfavor or exclude the other defendants' analog insulin is self-contradictory and nonsensical on its face. *See id.* ¶¶ 303, 311, 344, 352, 385, 393; *see also id.* ¶ 188. For example, if CVS Health formed an enterprise with Novo Nordisk to increase sales of Novo Nordisk's insulin products, CVS Health could not also be part of separate enterprises with Lilly and Sanofi to increase sales of their competing insulin products. The three alleged enterprises would have directly opposing interests and

could not simultaneously share the alleged exclusionary purpose. The Court should not credit internally contradictory allegations such as these on a motion to dismiss. *See, e.g.*, *Lind v. New Hope Prop., LLC*, 2010 WL 1493003, at *6 (D.N.J. Apr. 13, 2010) (dismissing plaintiffs' conspiracy claim where conclusory assertions were contradicted by factual allegations); *Payne v. DeLuca*, 433 F. Supp. 2d 547, 612 (W.D. Pa. 2006) (holding, among other reasons, that "self-contradictory" allegations were fatal to plaintiffs' claims).

Second, and for similar reasons, plaintiffs fail to adequately allege that defendants "conduct[ed] or participate[d], directly or indirectly, in the conduct of" a RICO enterprise's affairs. 18 U.S.C. § 1962(c). To satisfy this requirement, plaintiffs must plausibly allege that "defendants conducted or participated in the conduct of the '*enterprise's* affairs,' not just their *own* affairs." *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993). Where a plaintiff's allegations "are entirely consistent with . . . each [enterprise member] going about its own business" within "the bounds of the parties' normal commercial relationships," the conduct requirement is unsatisfied. *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 855 (7th Cir. 2013).

Plaintiffs cannot show that defendants participated in the conduct of a RICO enterprise by engaging in arm's-length negotiations with PBMs. This is simply the

negotiating framework inherent in *any* manufacturer-PBM relationship. Plaintiffs' allegations are "entirely consistent with [defendants and the PBMs] each going about [their] own business." *Id.* at 855. Crediting those allegations would effectively criminalize rebate negotiations across the entire pharmaceutical industry. That extreme position finds no support in RICO.

D. Plaintiffs Do Not Adequately Plead Proximate Causation

"[T]o state a claim under civil RICO, the plaintiff is required to show that a RICO predicate offense not only was a 'but for' cause of his injury, but was the proximate cause as well." *Hemi*, 559 U.S. at 9 (internal quotation marks and citation omitted); *see also In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633, 638 (3d Cir. 2015) ("The language of § 1964(c) requires a RICO plaintiff to show that the plaintiff suffered an injury to business or property and that the plaintiff's injury was caused by the defendant's violation of 18 U.S.C. § 1962." (footnote omitted)). Plaintiffs fail to allege proximate causation because defendants' supposed failure to disclose the "real price" of analog insulin—i.e., some measure of price net of rebates to PBMs—and how it differs from the "benchmark price" had no effect on the price that plaintiffs paid for insulin.

Under RICO, proximate causation requires a "direct relation" between the injury asserted and the alleged predicate acts. *Hemi*, 559 U.S. at 9 (quoting *Holmes*, 503 U.S. at 268). Proximate causation is absent if the plaintiff's alleged

injuries "could have resulted from factors other than [the defendants'] alleged acts of fraud." *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 459 (2006); *see also Hemi*, 559 U.S. at 11 (holding that proximate causation was absent where "the conduct directly causing the harm was distinct from the conduct giving rise to the fraud"). "When a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led directly to the plaintiff's injuries." *Anza*, 547 U.S. at 461; *see also, e.g.*, *Anderson v. Ayling*, 396 F.3d 265, 270 (3d Cir. 2005) (dismissing complaint for failure to allege proximate causation where there was, among other factors, "little indication of specific intent to harm plaintiffs").[26]

Plaintiffs fail to allege that defendants' alleged misrepresentations are the direct cause of their alleged injuries. At bottom, plaintiffs assert that defendants concealed "from the general public and consumers . . . the existence and amount of steep rebates [defendants] gave to the PBMs in exchange for preferred formulary

[26] Furthermore, where a RICO claim is based on predicate acts of mail or wire fraud, a plaintiff must plausibly allege that at least "someone relied on the defendant's misrepresentations." *Bridge*, 553 U.S. at 658-59; *Lynch v. Capital One Bank (USA), N.A.*, 2013 WL 2915734, at *3 (E.D. Pa. June 14, 2013) ("some form of reliance on the defendant's misrepresentation is necessary to properly establish proximate cause for a RICO violation based on mail or wire fraud").

positions" (*see* CAC ¶¶ 297, 338, 379) and the "lower, but secret, *real* price" that is "arrived at after deducting the manufacturer's 'rebate' to [the] PBMs." *Id.* ¶ 6.[27]

However, plaintiffs cannot show that disclosure of the "real price" would have changed the amounts they paid for analog insulin. Plaintiffs themselves allege that the point-of-sale price charged to an insured consumer is determined by the consumer's own PBM and insurer, and that the price charged to an uninsured consumer is determined unilaterally by the pharmacy. *Id.* ¶¶ 11 n.8, 190. They further allege that PBMs and pharmacies set prices based on defendants' benchmark price. *See id.* But plaintiffs do not allege that disclosure of the difference between the benchmark price and the "real price" (i.e., a price net of rebates) would have (i) changed the benchmark price itself, (ii) caused PBMs or pharmacies to set a different point-of-sale price for plaintiffs, or (iii) entitled plaintiffs to any corresponding rebate or discount. To the extent that plaintiffs are dissatisfied with their own insurers' failure to apply manufacturer rebates to reduce the prices that consumers pay at the point of sale, or with pharmacies' unilateral pricing decisions, their injury has "resulted from factors other than [the defendants'] alleged acts of fraud." *Anza*, 547 U.S. at 459.

[27] As noted above, the fact that brand name drug manufacturers pay rebates to PBMs has been public knowledge for many years. *See supra* at 16 n.17.

Numerous courts have rejected RICO claims where the alleged misrepresentations did not cause the plaintiffs' alleged injuries. As one district court has noted, a plaintiff cannot prove an injury (and thus lacks RICO standing) where "the rebates that were not disclosed had no effect on the decisions of the plaintiffs to incur [costs]." *Arthur*, 827 F. Supp. at 280. Likewise, here, defendants' supposed misrepresentations or omissions about "rebates" have no connection to the prices plaintiffs ultimately paid for insulin. Knowing the details of the rebates would not have entitled consumers to any corresponding discount, nor would it have in any other way altered the prices pharmacies charge at the counter—which, again, are not set by defendants. *See also Dow Chem. Co. v. Exxon Corp.*, 30 F. Supp. 2d 673, 695-96 (D. Del. 1998) (dismissing RICO claim where the plaintiff's "losses do not stem directly from [the] alleged misrepresentations").[28]

[28] This case thus presents the opposite of the situation in *Avandia*. There, the Third Circuit found RICO's proximate-causation requirement satisfied where the defendant manufacturer allegedly had misrepresented the safety of an insulin drug (Avandia) *directly* to the plaintiff third-party payors, which relied on the misrepresentation in deciding to "include[] Avandia in their formularies and cover[] Avandia at favorable rates in reliance on these misrepresentations." 804 F.3d at 636. The court held that "[t]he conduct that allegedly caused plaintiffs' injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint—the misrepresentation of the heart-related risks of taking Avandia that caused [plaintiffs] and PBMs to place Avandia in the formulary." *Id.* at 644. Unlike in *Avandia*, plaintiffs do not (and cannot) allege that defendants' alleged nondisclosure of rebates directly impacted their purchasing decisions.

II. The New Jersey Consumer Fraud Act Claims Should Be Dismissed for Failure to State a Claim

A. The Complaint Fails to Plead the "Deceptive Practices" and "Unconscionable Pricing" Claims with Specificity

Plaintiffs' NJCFA claims,[29] like their RICO claims, sound in fraud, and thus should be dismissed because they lack the particularity required by Rule 9(b). *See DeGennaro*, 2017 WL 2693881, at *5 ("The heightened pleading standard set forth in Rule 9(b) applies to plaintiff's [NJCFA] and common law fraud claims.").[30] Plaintiffs offer only unsupported allegations accusing defendants of "misrepresenting" or "concealing" pricing information, and claiming that defendants "knew, but did not disclose" information related to the cost of their insulin products and the existence and purpose of rebates. CAC ¶¶ 418-419, 434-435. Because plaintiffs do not identify with specificity how defendants violated the NJCFA, when and where any purported misrepresentations about "true prices"

[29] Plaintiffs bring three claims under the NJCFA: one against Sanofi for deceptive practices (Count Four), one against Novo Nordisk for deceptive practices (Count Five), and one against Lilly, Sanofi, and Novo Nordisk for unconscionable business practices (Count Six). Each claim fails for the reasons set forth in this section. Separately, plaintiffs assert a cursorily pleaded, duplicative NJCFA claim against all defendants (Count Forty) that fails for the same reasons.

[30] Plaintiffs' allegations of "unconscionable" pricing practices arise out the same alleged course of conduct as their other NJCFA claims and RICO claims. *See* CAC ¶¶ 439-448. "Because the underpinning of [plaintiffs' NJCFA] claim is fraud," Rule 9(b) applies to their unconscionable practices claim as well. *Gray v. Bayer Corp.*, 2009 WL 1617930, at *2 (D.N.J. June 9, 2009).

were made, or who made any such statements, the NJCFA claims must be dismissed.

B. The Complaint Does Not Plead Unlawful Conduct by Defendants

Plaintiffs have failed to plead any unlawful conduct by defendants. Plaintiffs' allegations are predicated on alleged "deceptive" and "unconscionable" practices. *See, e.g., id.* ¶¶ 418, 434, 448. The "capacity to mislead is the prime ingredient of deception or an unconscionable commercial practice." *Sickles v. Cabot Corp.*, 877 A.2d 267, 276 (N.J. Super. Ct. App. Div. 2005). As shown above, plaintiffs have failed to identify any actions by defendants that were capable of misleading consumers as to analog insulin pricing or rebates. *See id.* at 277 (dismissing NJCFA claim where plaintiff "failed to set forth any factual allegations to demonstrate a capacity to mislead").

Moreover, because plaintiffs have not identified a single affirmative misrepresentation or omission of material fact by any defendant, much less all of them, plaintiffs cannot state a claim for a "deceptive" practice. *See Billings v. Am. Express Co.*, 2011 WL 5599648, at *9 (D.N.J. Nov. 16, 2011) (explaining that "affirmative misrepresentation[s]" and "knowing omission[s] . . . accompanied by an intent that others rely upon the omission" constitute unlawful conduct).

Plaintiffs' allegations of "unconscionable" pricing similarly fail. New Jersey courts have uniformly rejected the notion that allegedly "excessive prices"

themselves constitute an unconscionable commercial practice. *See, e.g.*, *Quigley v. Esquire Deposition Servs., LLC*, 975 A.2d 1042, 1048 (N.J. Super. Ct. App. Div. 2009) ("Plaintiff has not cited any authority for his argument that a Consumer Fraud Act claim may be stated solely by an allegation that the price of a product was excessive . . . ."); *Yingst v. Novartis AG*, 63 F. Supp. 3d 412, 416 (D.N.J. 2014) (dismissing NJCFA claim where plaintiff's "only contention [was] that [d]efendant engaged in an unconscionable commercial practice by charging a higher price").[31] Conduct that merely causes "consumer dissatisfaction" is not unconscionable. *Billings*, 2011 WL 5599648, at *9.

[31] The cases cited in the complaint do not suggest otherwise. *See* CAC ¶ 441 n.86. In each of these cases, plaintiffs alleged that defendants had engaged in deceptive marketing aimed at vulnerable consumers and failed to deliver the goods or services that were promised, *in addition to* charging an allegedly excessive price. *Kugler v. Romain*, 279 A.2d 640, 651-53 (N.J. 1971) (defendants engaged in door-to-door canvassing, selling "educational packages" that were "practically worthless for that purpose" at an "exorbitant price"); *In re Nat'l Credit Mgmt. Grp.*, 21 F. Supp. 2d 424, 452-53 (D.N.J. 1998) (defendant "prey[ed] upon economically disadvantaged individuals" and charged "grossly excessive" fees for credit screening while "provid[ing] services of limited value in return"); *In re Fleet*, 95 B.R. 319, 336 (E.D. Pa. 1989) (defendants marketed financial counseling services that it "could not and did not provide" to "financially troubled and distraught" consumers, then charged consumers an excessive fee "simply for referring them to an attorney"); *Pro v. Hertz Equip. Rental Corp.*, 2012 WL 12906183, at *1 (D.N.J. June 25, 2012) (defendants deceptively collected $151 million in coverage fees for car rentals, but only provided coverage for a small number of loss claims).

C. The Complaint Does Not Allege that Plaintiffs Suffered Any "Ascertainable Loss"

The NJCFA claims also fail because plaintiffs have not established (and cannot establish) the "ascertainable loss" required by the statute. To show "ascertainable loss," a plaintiff must show one of the following: (1) that the "product received was essentially worthless," under the "out-of-pocket theory," or (2) that she was "misled into buying a product that [was] ultimately worth less than the product that was promised," under the "benefit of the bargain theory." *DeGennaro*, 2017 WL 2693881, at *7 (citations omitted). A plaintiff who seeks to demonstrate ascertainable loss under the "benefit of the bargain theory" must allege both a "reasonable belief about the product induced by a misrepresentation" and also that the "difference in value between the product promised and the one received can be reasonably quantified." *In re Gerber Probiotic Sales Practices Litig.*, 2014 WL 3446667, at *3 (D.N.J. July 11, 2014) (citation omitted). A "failure to quantify this difference in value results in the dismissal of a claim." *Id.*

The complaint fails to state any claims under the NJCFA because it does not plead ascertainable loss. *See DeGennaro*, 2017 WL 2693881, at *6. It does not state claims under the "out-of-pocket" theory because it contains numerous allegations that show the significant value of insulin to individuals with diabetes, which preclude any inference that the medication is "worthless." *See id.* at *7. Indeed, plaintiffs repeatedly emphasize that insulins produced by defendants are

"unquestionably the best course of treatment" for those with Type I diabetes and the "most convenient initial insulin regimen" for those with Type II diabetes. CAC ¶¶ 234-238 (quotation omitted).

Nor does the complaint state a claim under the "benefit of the bargain" theory. Indeed, plaintiffs make no attempt to allege that they were misled about any of the benefits of insulin, and their conclusory assertions that defendants "inflate" the prices of insulins (*e.g.*, *id.* ¶¶ 2, 24) rest solely on allegations that the price paid by certain consumers is (not surprisingly) higher than the price paid by some insurers and the average net price received by the manufacturer. Instead of alleging that they were misled about the benefits of insulin, plaintiffs allege that defendants made unspecified misleading statements and omissions regarding "the true cost of insulin"—which is, among other problems, incoherent. *See*, *e.g.*, *id.* ¶ 273.

Plaintiffs do not allege any "reasonable belief about [insulin] induced by a misrepresentation" or that there was any "difference in value between the [insulin] promised and the [insulin] received"—much less that any such difference "can be reasonably quantified." *In re Gerber*, 2014 WL 3446667, at *3. Therefore, plaintiffs have failed to allege an ascertainable loss under the "benefit of the

bargain" theory.[32] *See, e.g., Truglio v. Planet Fitness, Inc.*, 2016 WL 4084030, at *8 (D.N.J. July 28, 2016) (holding that plaintiff had failed to "plausibly allege that there is a difference in value between the gym membership [she was] promised . . . and the one received . . . or that such difference can be reasonably quantified"); *see also Franulovic v. Coca Cola Co.*, 2007 WL 3166953, at *8-10 (D.N.J. Oct. 25, 2007) (explaining that "broad and conclusory allegations are not sufficient to demonstrate an ascertainable loss" under the NJCFA (citation omitted)).

In effect, plaintiffs' NJCFA claims rely on a novel and exceedingly amorphous "price inflation" theory. But New Jersey courts have expressly rejected attempts to rely on such theories in the NJCFA context. *See Dugan v. TGI Fridays, Inc.*, 171 A.3d 620, 640 (N.J. 2017) (noting decisions explaining that permitting plaintiffs to rely on such a theory would "effectively eliminate the

[32] Some judges in this District have identified "nominal overcharge" as a third category of ascertainable loss in dictum. *See, e.g., Truglio*, 2016 WL 4084030, at *6. However, that treatment of ascertainable loss appears to be a misinterpretation of New Jersey law. Courts discussing "nominal" charges have done so in the context of the type of loss for which class actions are an appropriate mechanism, rather than as a third cognizable type of loss. *See Lee v. Carter-Reed Co.*, 4 A.3d 561, 583 (N.J. 2010) (explaining that a class action was a "superior adjudicative method" for resolving claims due in part to the nominal value of each class member's claim); *Bosland v. Warnock Dodge, Inc.*, 964 A.2d 741, 751 (N.J. 2009) ("When confronted, as we are here, with a plaintiff who asserts that she was the victim of an overcharge which itself is small in amount, and who seeks recovery for herself and on behalf of numerous others with 'nominal' claims, we cannot overlook the reality that, without the remedy that the [NJCFA] affords, all of those wrongs might go unvindicated.").

ascertainable loss and causation requirements that differentiate consumer CFA claims from Attorney General enforcement actions under the statute"). Thus, courts dismiss NJCFA claims where it is clear that plaintiffs are attempting to rely on a "price inflation" theory in lieu of a concrete showing of ascertainable loss, and plaintiffs' NJCFA claims should be dismissed for that reason as well. *See, e.g.*, *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604, at *20-21, *31(D.N.J. July 10, 2009); *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 178-79 (N.J. Super. Ct. App. Div. 2003).

CONCLUSION

For the foregoing reasons, defendants respectfully request that the RICO claims and the NJCFA claims in the Consolidated Amended Class Action Complaint be dismissed with prejudice.

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Respectfully submitted,

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